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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/089,871	06/04/1998	RUDOLF CAROLUS MARIA BARENDSE	97253-A	3289

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EXAMINER	
RAMIREZ, DELIA M	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/089,871	BARENDSE ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,19,21-28,31-35 and 41-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,19,21-28,31-35 and 41-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 18-19, 21-28, 31-35, and 41-52 are pending.

Applicant's amendment of claims 18-19, and addition of claims 41-52 as submitted in a communication filed on 4/14/2006 is acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112, first paragraph

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 18-19, 21-28, 31-35, and 41-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection necessitated by amendment.

Claims 18-19 (claims 21-28, 31-35 and 41-52 dependent thereon) as amended are now directed to a phytase granulate or composition thereof, wherein the granulate is prepared by extrusion and the granulate does not contain fibrous materials. Applicants point to page 6, lines 19-20 of the specification as support for the amended claims. While the Examiner agrees that there is support for extrusion as the method to prepare the granulate, the Examiner is unable to find support for a granulate which does not contain fibrous materials. The specification provides support for a non-fibrous carrier in the granulate but there is no support for the entire granulate to lack fibrous materials. If the carrier defines the entire structure of the granulate such that lacking fibrous materials in the carrier would also result in the entire

granulate to lack fibrous materials, it is noted that claims 18-19 already recite "non-fibrous solid carrier". Thus, based on what has been disclosed in the specification, there is no indication that a granulate as claimed which lacks fibrous materials, and compositions thereof, were within the scope of the invention as conceived by Applicants at the time the application was filed. Accordingly, Applicants are required to cancel the new matter in response to this Office Action.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 18-19, 21, 24-28, 31-35 remain rejected and new claims 41-45, 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996). This rejection as it applies to new claims 41-45, 48-52 is necessitated by amendment.

5. Claims 22-23 remain rejected and new claims 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996) as applied to claims 18-19, 21, 24-28, 31-35, 41-45, 48-52 above, and further in view of Markussen et al. (U.S. Patent No. 4106991, 1978). This rejection as it applies to new claims 46-47 is necessitated by amendment.

6. Claims 18-19, 21-22, 24-28, 31-35 remain rejected and new claims 41-46, 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996), and further in view of Haarasilta (GB 2-139868A, 1984). This rejection as it applies to new claims 41-46, 48-52 is necessitated by amendment.

7. Claim 23 remains rejected and new claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No.

6120811, filed 10/4/1996) and Haarasilta (GB 2-139868A, 1984) as applied to claims 22 and 46, and further in view of Markussen et al. (U.S. Patent No. 4106991, 1978). This rejection as it applies to new claim 47 is necessitated by amendment.

8. These rejections have been discussed at length in Paper No. 30, mailed on 2/24/2003, Paper No. 33, mailed on 11/3/2203, the Advisory Action mailed on 6/3/2004, the Final Action mailed on 2/22/2005, and the Non Final Action mailed on 1/11/2006. They are applied to new claims 41-52 for the reasons of record and those set forth below.

9. Claims 18-19 have been amended such that they now require extrusion for the preparation of the granulate and limit the granulate to one which does not contain fibrous materials. New claims 41-43 are directed to compositions comprising the granulate of claim 19 wherein the compositions are edible feed compositions or animal feed compositions. Claim 44 is directed to the composition of claim 41 wherein the composition comprises one or more feed substances or ingredients mixed with the granulate. Claims 45-46 are directed in part to the granulate of claim 18 wherein the granulate comprises a gel-forming compound or an edible oil. Claim 48 is directed to the granulate of claim 18 wherein the granulate additionally comprises an endo-xylanase and/or a β-glucanase, whereas claim 49 adds the limitation that the granulate additionally comprises starch. Claim 50 adds the limitation that the phytase of claim 18 is not heat tolerant and claims 51-52 add the limitations that the phytase of claim 18 is derived from fungus or derived from *Aspergillus*. Claim 47 is drawn in part to the phytase-containing granulate of claim 18, further comprising carboxy-methyl cellulose (CMC).

10. The claimed invention is deemed obvious over the teachings of Nielsen et al., Ghani, Haarasilta and Markussen et al. as previously discussed for the following reasons. Nielsen et al. teach extrusion as one of the methods for the preparation of granulates containing enzymes (page 10, lines 25-26). In addition, Haarasilta teaches extrusion (page 1, lines 42-43) of feed compositions to be used as feedstuff for ruminants. With regard to the limitation requiring the granulate to lack fibrous materials, it is noted

that as previously discussed, Ghani teaches an enzyme granulate and compositions thereof, wherein a solid carrier can be a starch-containing compound (column 2, lines 25-34). In one of the examples provided by Ghani, the carrier contains 90% (w/w) of soy flour (column 6, lines 43-48; 10 g corn syrup per 100 g soy flour). Corn syrup would lack fibrous materials. Therefore, it would have been obvious to one of ordinary skill in the art to prepare a granulate lacking fibrous materials using extrusion, as now recited in the claims. A person of skill in the art would be motivated to use extrusion since extrusion is a widely used mechanical method to produce granulates. Also, a person of ordinary skill in the art would be motivated not to use fibrous materials in the granulate (1) to avoid mechanical malfunctions in the extruder, and (2) to produce smaller granules as the presence of fibrous materials may interfere with obtaining granules which are smaller than the average size of the fibrous material. One of skill in the art has a reasonable expectation of success at using extrusion since this method is commonly used in the industrial preparation of granules. Also, one of skill in the art has a reasonable expectation of success at making granulates which lack fibrous materials since Ghani clearly teaches enzymes granulates which lack fibrous materials. Thus, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

11. Applicants traverse the rejections of claims (a) 18-19, 21, 24-28 and 31-35 over Nielsen et al. in view of Ghani, (b) 22-23 over Nielsen et al. in view of Ghani, and further in view of Markussen, and (c) 18-19, 21-22, 24-28, 31-35 over Nielsen et al. in view of Ghani, and further in view of Haarasilta. According to Applicants, none of these references describe an extruded granulate that does not contain fibrous materials. Applicants submit that while Nielsen describes extrusion of a feed, such feed contains fibrous materials as the feed would contain vegetables which are inherently fibrous. With regard to the teachings of Ghani, Applicants argue that Ghani does not teach extrusion but rather gentler preparation methods. Thus, according to Applicants, a skilled artisan would not necessarily choose extrusion for a granulate which contains an enzyme and does not contain a fibrous carrier. Applicants also argue that

fibrous carriers generally stabilize the granules and that one of skill in the art would not expect to successfully form stable granulates without fibrous carriers. With regard to Haarasilta, Applicants argue that this reference while teaching extrusion of foodstuffs comprising fibrous components, does not teach extrusion of granulates which comprise enzymes. According to Applicants, enzymes are sensitive to processing conditions and rapidly lose their activity if not treated carefully. Applicants point out that Haarasilta teaches that adding hay or straw in their granulate is necessary for the proper action of the rumen.

With regard to claim 19, Applicants cite case law in support of the argument that unless the reference disclosing the genus points specifically to the species recited in the claims, the genus disclosed does not render the species unpatentable. Applicants submit that Ghani does not disclose a specific divalent metal ion. Applicants also point out that in Haarasilta, the presence of inorganic salts is to assist in forming stable granules resisting decomposition in rumen conditions. Thus, according to Applicants, a skilled artisan would not be motivated to arrive to the invention of claim 19 because the present claims are directed to granules which do not contain the fibrous material needed for appropriate rumen conditions as taught by Haarasilta.

12. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the previous rejections or avoid the rejection of new claims 41-52. The Examiner acknowledges that neither Nielsen et al. nor Haarasilta teach the extrusion of granulates lacking fibrous materials. The Examiner also acknowledges that the granulates of Haarasilta comprise fibrous materials since they are used as fodder for cattle. However, as previously indicated and admitted by Applicants, Nielsen et al. teach extrusion of granulates which comprise enzymes. Therefore, while it is agreed that some enzymes may be more susceptible to damage as a result of extrusion, there is no evidence in the prior art or by Applicants which suggests that enzymes or phytases can not withstand granulation by extrusion. Therefore, it is not unreasonable for one of skill in the art to expect a phytase in a phytase-containing

granulate made by extrusion to be enzymatically active. Also, as evidenced by Nielsen and Haarasilta, the art clearly teaches that extrusion is a very common method to produce granulates (with and without enzymes). Thus, not only there is a motivation to use extrusion, which is a very common method for producing granulates, but there is also a reasonable expectation of success at producing phytase-containing granulates by extrusion since the art teaches other enzyme-containing granulates made by extrusion.

With regard to arguments that fibrous carriers generally stabilize the granules and that one of skill in the art would not expect to successfully form stable granulates without fibrous carriers, it is noted that while one could agree that having fibrous carriers may result in a more stable granulate, there is no evidence in the prior art or by Applicants which show that no granulate can be formed by extrusion without fibrous materials, or that the presence of the fibrous material affects enzymatic activity. There is no disclosure in the specification showing unexpected results regarding the formation of enzymatically active phytase-containing granulates lacking fibrous materials by extrusion. Furthermore, as indicated above, one of skill in the art would be motivated not to use fibrous materials in the granulate (1) to avoid mechanical malfunctions in the extruder, and (2) to produce smaller granules as the presence of fibrous materials may interfere with obtaining granules which are smaller than the average size of the fibrous material. Also, as indicated previously, Ghani teaches the use of carriers having 90% soy flour and 10% corn syrup. Thus, one of skill in the art would be motivated to use carriers, such as those of Ghani, containing edible carbohydrates to further increase the nutritional value of the granulate.

Arguments regarding the rejection of claim 19 and how the teachings of Ghani and Haarasilta do not render the claimed invention obvious are not persuasive. The Examiner acknowledges the cited case law and agrees that Ghani does not teach a specific divalent cation or Zn cations. However, it is noted that the teachings of Ghani with regard to metal salts were introduced to show that granulates which contain metal salts are well known in the art. The Examiner is not relying on Ghani et al. to show

motivation with respect to Zn ions. Instead, the Examiner explained the reasons why motivation to use Zn salts and expectation of success at adding Zn salts is found in the knowledge generally available to one of ordinary skill in the art.

Even if one were to assume that the teachings of Nielsen et al. in view of Ghani do not render obvious the granulate of claim 19, it is reiterated herein that Haarasilta teach granulates containing inorganic salts having divalent cations. Arguments indicating that the presence of inorganic salts in the granulate of Haarasilta is to assist in forming stable granules resisting decomposition in rumen conditions and thus, would not lead one of skill in the art to arrive to the invention of claim 19 are not found persuasive. The Examiner is not contending that the granulate of Haarasilta has been disclosed as being used as fodder for cattle. However, the presence of inorganic salts in the granulate of Haarasilta does not appear to be solely for aiding in the granulation process. As taught by Haarasilta, the feedstuff from which the granulate is made contains not only hay and/or straw, but also proteins, carbohydrates, vitamins, and minerals (page 1, lines 60-61). Calcium is well known mineral used to increase the nutritional value of feed and food. Addition of calcium salts while aiding in the granulation process is also providing a mineral which is well known as a nutritional additive. Thus, not only one of skill in the art would be highly motivated to add calcium to a granulate to increase its nutritional value, but there is also a reasonable expectation of success at adding calcium to a granulate, as taught by Haarasilta. Therefore, the invention of claim 19 is deemed obvious over the prior art of record.

Conclusion

13. No claim is in condition for allowance.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
May 10, 2006

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